



VIRGINIA SEAFOOD COUNCIL • 76 Raleigh Rd. • Newport News, VA 23601 • (757) 595-6603 • Fax (757) 596-8771

April 19, 1999

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Dear Branch Manager:

The Virginia Seafood Council request denial, in total, of the petition from the Center for Science in the Public Interest on the subject of nondetectable levels of *Vibrio vulnificus* in some raw molluscan shellfish. The Virginia Seafood Council represents all facets of the Virginia oyster industry -- grower, harvester, processor, and retailer. I offer these comments in response to the request for information and views from the general public published in the Federal Register, Volume 64, Number 13, page 3300, Thursday, January 21, 1999.

Under Section 402(a)(1) of Federal Food Drug and Cosmetic Act (FFDCA), foods are not considered adulterated by a poisonous or deleterious substance if "naturally occurring" and "not ordinarily injurious." There is ample evidence cited in the CSPI petition which proves that *Vibrio vulnificus* is an organism which is naturally occurring in molluscan shellfish and is not ordinarily injurious. Therefore, adopting a standard of nondetectable is not necessary and is not reasonable.

The Virginia Seafood Council is always concerned about issues of public health and takes the industry's responsibility on public health very seriously. The Council considers the illness or death of any person as a result of shellfish consumption unfortunate and regrettable and supports the taking of any reasonable, science based actions to prevent such an occurrence. In the case of V.v. all information confirms that illnesses occur in an individual who is vulnerable due to deficiencies which make the individual susceptible on a specific occasion.

Shellfish containing V.v. are not contaminated or adulterated and do not cause illness in the vast majority of consumers. Raw shellfish are clearly marketed as a "raw" product and consumers recognize there may be an element of risk that cooking will eliminate. Persons with specific at-risk conditions know their vulnerability. The Virginia Seafood Council stands opposed to

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consumption of raw molluscan shellfish by any person who is at-risk due to his or her own underlying immune system problems.

The vast majority of consumers can eat the same product without fear of illness or death. The Virginia Seafood Council does not believe that the industry bears the responsibility for complying with a standard of nondetectable for all products to make them safe for all consumers, few of whom may have immune system problems.

The Virginia Seafood Council recognizes that FDA already has on file all *Vibrio vulnificus* court cases and results. I believe you are receiving comments from other oyster industry representatives who will review some of the court decisions.

Establishment of a zero tolerance policy on *Vibrio vulnificus* will have devastating economic impact on the oyster industry.

We appreciate the opportunity to offer these comments, will welcome the opportunity to discuss the issue at your request, and formally request that FDA deny the petition from the Center for Science in the Public Interest regarding tolerance levels of *Vibrio vulnificus*.

Sincerely yours,



Frances W. Porter  
Executive Director

cc: Virginia Congressmen Bateman, Pickett, Scott, Sisisky  
Virginia Senators Robb and Warner